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GUIDELINES FOR REQUESTING APPROVAL FOR CADAVER RESEARCH FROM NHTSA

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October 16, 1979

Congressional hearings on the subject of the use of cadavers in automotive safety have resulted in the establishment of a set of guidelines for cadaver testing by NHTSA. These guidelines are incorporated in DOT Order No. 700-4. This write-up is a discussion of the documents needed to obtain approval for the use of cadavers under NHTSA sponsored contracts.

Although Order No. 700-4 is an internal DOT document, it affects all NHTSA contractors who intend to do cadaver research. They should assume some of the responsibilities of the Contract Technical Manager and prepare an application to comply with this order.

The first document to be submitted is entitled Benefit Assessment. In it the aims of the research are delineated. Reasons why cadavers are best suited for this research as opposed to other surrogates should be enumerated. There should also be a statement with respect to the effect of this research on rule-making by NHTSA. The means for disseminating data and where it will be published should be included along with a statement indicating that as much data as possible will be acquired from each test to minimize the number of tests and cadavers used. Finally, the Benefit Assessment should contain a summary of the documents to be submitted. These will include the criteria for selection of cadavers to get optimum data as well as affirmation that cadavers will be treated with respect and other ethical statements. Legal requirements for the use of cadavers as stipulated by State law should also be incorporated.

With respect to the criteria for cadaver selection, the major consideration should be the cause of death as it may be indicative of the strength of the skeletal structure. As far as safety of personnel is concerned, cadavers should not be used if an infectious disease was present at the time of death. Very aged specimens must also be excluded because of the possibility of osteoporosis. A brief discussion of these factors should follow.

The approval of the research protocol by the institutional review board

must be transmitted to NHTSA in a statement signed by the appropriate institution official. For example, Wayne State uses the HEW form No. 596. It is the standard form used for NIH grants to report that a certain research protocol has been approved by the institutional review board. However, any formal statement conveying this approval will probably be acceptable to NHTSA. It should be noted that if the Board considers the proposed research to be within the normal scope of teaching and research, in the context of the appropriate local statutes, a statement to this effect should be included. If it is not included the interim guidelines of the Association of Anatomy Chairman requires next-of-kin approval. Finally, a letter indicating that the needs of medical education have first priority and that this research will not interfere with those needs must be submitted. This letter should have the approval of the chairman of the Anatomy Department of the institution supplying the cadavers. The above points constitute the ethical aspects of cadaver research.

Another document should delineate the procedures for handling unembalmed cadavers because of the the danger of contamination of personnel, equipment, instruments, and the infection of people touching contaminated surfaces. The following points should be covered to demonstrate to NHTSA that qualified personnel will handle unembalmed cadavers:

- 1) Personnel will be instructed in handling of cadavers.
- 2) Precautions will be taken with respect to storage; duration of storage; duration of exposure outside the cold storage area.
- 3) Precautions to be taken during instrumentation and the experiment itself.

Another document should specify the legal requirements for the handling and use of cadavers. This should be prepared by the Office of the General Counsel or its equivalent which can investigate the legal aspects of cadaver research. This document should consist of the regulations for the donation of bodies as specified in the uniform anatomical gift act of the state. It

should also designate the individuals or department responsible for keeping permanent records of pertinent information regarding each cadaver. The Office of the General Council should also investigate the various city ordinances in addition to the state statutes governing the transportation of cadavers over city roads. For example, there may be regulations with respect to transportation over county lines.

The question of the proper disposal of cadavers should be discussed. This must be in conformity with the regulations of the Anatomy Committee of the state. This discussion should extend to unclaimed bodies if they are to be used.

In summary, the following material must be submitted before cadaver research can be approved under any DOT contract:

- 1) Benefit assessment
- 2) Criteria for the selection of cadavers
- 3) Approval of the institutional review board - including the following statements
 - the research is within (or outside) the scope of normal teaching and research.
 - it is within the appropriate local statutes.
- 4) Procedures for the handling of cadavers and training of personnel
- 5) Legal requirements that are required by NHTSA guidelines.

STATEMENT OF ETHICAL PRACTICES
ON CADAVER USAGE

Affirmation Form

Wayne State University requires that the following principles be adhered to in any laboratory in which research utilizing cadavers is conducted:

1. The cadavers shall be treated with the greatest respect and handled with dignity.
2. Cadavers shall not be used in tests or experiments which are not essential to research goals.
3. Cadavers shall not be subject to unnecessary exposure or damage.
4. Individual identities shall not be revealed by name, photographic record, or other means.
5. Cadavers shall be obtained, handled, and disposed of in accordance with the governing legal requirements.

Wayne State University requires that all researchers who use cadavers in their research subscribe to the above principles and attest to them by the following form:

Believing in the essential dignity of man in body and spirit, while recognizing the necessity for the study of human bodies to advance the understanding of human life towards the goal of improving and preserving life, we subscribe to these tenets:

In any laboratory with which we are associated, we shall treat human remains with the greatest care and respect, never subjecting them to tests that are not essential to our research goals, always maintaining them in a proper condition, avoiding unnecessary exposure and damage, in no case revealing identities, always avoiding any frivolities, and finally returning them for proper burial or disposal.

DATE _____

SIGNATURE _____

NAME

INTERIM GUIDELINES FOR USE OF CADAVERS
IN BIOMEDICAL RESEARCH

1. The protocols for all research proposals should be evaluated and approved by the institutional review board on human experimentation or by a comparable ad hoc committee convened for this purpose. This committee, which should consist of representatives of appropriate departments, would have the dual responsibility of approving the research protocols and of designating procedures for overseership.
2. After a proposal is approved by the institutional review board, reasonable effort should be made to obtain next-of-kin approval for the research that is considered by the board to be beyond the normal scope of teaching and research within the context of the appropriate local statutes.
3. A member of the Department of Anatomy is to be assigned the responsibility of overseeing the research program. It is his job to ensure that the cadavers are handled with respect and that the protocols approved by the medical school review committee are being followed.
4. The identity of the cadaver is not disclosed.
5. Cadavers and dissected parts not needed for further teaching or research should be returned to the appropriate authority (e.g., Medical Examiner's Office or Anatomy Department) for cremation or burial.
6. Publicity should be minimized. Press interviews should be avoided in favor of written press releases in order that such statements can receive prior approval of the Department of Anatomy and/or the appropriate oversight committee.

(Adopted by Association of Anatomy Chairmen, October, 1978)